TABLE 3

Chemical Stability Comparison

		Monofumarate form		Hemifumarate form	
Storage Condition	Time Points (weeks)	% TA* Area Normalized	% Total Deg. Products	% TA Area Normalized	% Total Deg. Products
40° C./	0	97.1	0.69	98.4	0.05
75% RH	1	97.0	0.87	98.4	0.14
Cap	2	96.6	1.18	98.5	0.14
Closed	4	96.4	1.49	98.4	0.25
	8	95.4	2.36	98.0	0.49
40° C./	0	97.1	0.69	98.4	0.05
75% RH	1	96.9	0.90	98.5	0.15
Cap	2	96.6	1.10	98.5	0.14
Open	4	96.2	1.67	98.4	0.26
	8	95.0	2.74	98.1	0.50
70° C.	0	97.1	0.69	98.4	0.05
Cap	2	96.2	1.83	98.5	0.22
Closed	4	93.3	4.78	98.4	0.33

*TA is tenofovir alafenamide

Thermodynamic Stability

Stable form screening of tenofovir alafenamide hemifumarate showed that it is thermodynamically stable in most solvents, such as ACN, toluene, ethyl acetate, methyl tert-butyl ether (MTBE), acetone, THF, and 2-methyl THF. A similar stable form screening of the monofumarate form showed that this form is not thermodynamically stable in the above-listed solvents. When suspended in these solvents, the monofumarate form of tenofovir alafenamide fully converts to the hemifumarate form in THF and 2-methyl THF, and partially converts to the hemifumarate form in ACN, ethyl acetate, MTBE, and acetone, as well as at ambient temperatures.

Thermal Stability

As shown by the DSC data, the hemifumarate form of tenofovir alafenamide has a melting point that is about 10° C. higher than that of the monofumarate form, indicating that the hemifumarate form has improved thermal stability as compared with the monofumarate form.

All publications, patents, and patent documents are incorporated by reference herein, as though individually incorporated by reference. The invention has been described with reference to various specific and preferred embodiments and techniques. However, it should be understood that many variations and modifications may be made while remaining within the spirit and scope of the invention.

What is claimed is:

1. A composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate.

2. The composition of claim **1**, wherein the composition comprises less than about 1% by weight of tenofovir alafenamide monofumarate.

3. The composition of claim **1**, wherein the composition comprises less than about 0.5% by weight of tenofovir alafenamide monofumarate.

4. The composition of claim **1**, wherein the ratio of fumaric acid to tenofovir alafenamide in said composition is 0.5±0.1.

5. The composition of claim **1**, wherein the ratio of fumaric acid to tenofovir alafenamide in said composition is 0.5±0.01.

6. The composition of claim **1**, having an X-ray powder diffraction pattern that comprises 2theta values of 6.9±0.2° and 8.6±0.2°.

7. A pharmaceutical composition comprising the composition of claim **1** and a pharmaceutically acceptable excipient.

8. The pharmaceutical composition of claim **7**, further comprising an additional therapeutic agent.

9. The pharmaceutical composition of claim **8**, wherein the additional therapeutic agent is selected from the group consisting of human immunodeficiency virus (HIV) protease inhibiting compounds, HIV nonnucleoside inhibitors of reverse transcriptase, HIV nucleoside inhibitors of reverse transcriptase, HIV nucleotide inhibitors of reverse transcriptase, HIV integrase inhibitors, and CCR5 inhibitors.

10. A method for treating a human immunodeficiency virus (HIV) infection comprising administering to a subject in need thereof a therapeutically effective amount of the composition of claim **1**.

11. A method for treating an HIV infection comprising administering to a subject in need thereof a therapeutically effective amount of the pharmaceutical composition of claim **7**.

12. The method for treating an HIV infection of claim **10**, further comprising administering to the subject one or more additional therapeutic agents selected from the group consisting of human immunodeficiency virus (HIV) protease inhibiting compounds, HIV nonnucleoside inhibitors of reverse transcriptase, HIV nucleoside inhibitors of reverse transcriptase, HIV nucleotide inhibitors of reverse transcriptase, HIV integrase inhibitors, and CCR5 inhibitors.

13. A method for treating a hepatitis B virus (HBV) infection comprising administering to a subject in need thereof a therapeutically effective amount of the composition of claim **1**.

14. A method for treating an HBV infection comprising administering to a subject in need thereof a therapeutically effective amount of the pharmaceutical composition of claim **7**.

15. A method for preparing a pharmaceutical composition comprising combining the composition of claim **1** and a pharmaceutically acceptable excipient to provide the pharmaceutical composition.

16. The method for treating an HIV infection of claim **10**, wherein the composition is administered in multiple daily doses.

17. The method for treating an HIV infection of claim **10**, wherein the composition is administered in a single daily dose.

18. The method for treating an HBV infection of claim **13**, wherein the composition is administered in multiple daily doses.

19. The method for treating an HBV infection of claim **13**, wherein the composition is administered in a single daily dose.

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